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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/618,540	07/09/2003	Sai Kiang Lim	4810-66314	8220

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EXAMINER

BARNHART, LORA ELIZABETH

ART UNIT PAPER NUMBER

1651

DATE MAILED: 11/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/618,540

Applicant(s)

LIM, SAI KIANG

Examiner

Lora E. Barnhart

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2005.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 18 and 19 is/are pending in the application.
4a) Of the above claim(s) 19 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-4 and 18 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☒ The drawing(s) filed on 29 September 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

The reply received 9/29/05 amending claims 1 and 2, canceling previously withdrawn claim 12, and adding claims 18 and 19 is acknowledged. Claims 5-11 and 14-17 remain withdrawn by the examiner. Claims 1-4, 18, and 19 are pending.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Prior art references can be found in a prior Office action, unless otherwise noted.

Election/Restrictions

The examiner notes that applicant continues to traverse the restriction requirement, but since said requirement was properly made FINAL on the Office action mailed 6/27/05, such continued traverse is improper. The restriction requirement remains FINAL.

Newly submitted claim 19 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: It is drawn to a method of making the composition of claim 1 and, as such, would have been placed into Group II in the restriction requirement mailed 5/10/05. Applicant did not specifically traverse the restriction of Group I from Group II in the response to said requirement, which was received 6/13/05. As such, the election of Group I over Group II has been treated as an election without traverse.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 19 is withdrawn

Art Unit: 1651

from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Examination will continue on claims 1-4 and 18 ONLY.

Specification

The amendments to the specification are noted and accepted.

Drawings

The drawings were received on 9/29/05. These drawings are acceptable.

Double Patenting

Claims 1-4 remain provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-3 of copending Application No. 10/521071, which at this time is not available to the examiner. This rejection is based on the claims in the corresponding WIPO document (PCT/SG2003/000169) of which the co-pending application is the 35 U.S.C. § 371 filing.

This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

The examiner notes applicant's assertion that "there [will be] no unjustified extension of patent exclusivity beyond the term of patent(s) that may issue" (Remarks, page 9, section IV), but notes that the claims still require a rejection under section 101 as detailed above.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined

Art Unit: 1651

application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claim 18 is provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 10/521071, which at this time is not available to the examiner. This rejection is based on the claims in the corresponding WIPO document (PCT/SG2003/000169) of which the co-pending application is the 35 U.S.C. § 371 filing.

Although the conflicting claims are not identical, they are not patentably distinct from each other because the scope of instant claim 18 is completely encompassed by the scope of claims 1-3 of the '071 application. Instant claim 18 requires that the cells of claim 1, which are identical to the cells of claim 1 of the '071 application as claimed, be from a single clone. Because the '071 claims do not limit the source of cells, they therefore encompass cells obtained from any source that meet all the limitations of said claims.

Art Unit: 1651

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 112

The rejection of claims 1-4 under section 112, first paragraph, as failing to be enabled by the specification is withdrawn in light of the amendments to the claims and of applicant's remarks.

The rejection of claims 1-4 under section 112, first paragraph, as failing to comply with biological deposit requirements is withdrawn in light of applicant's remarks.

The rejection of claims 1-4 under section 112, second paragraph, are withdrawn in light of the amendments to the claims and of applicant's remarks.

Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 18 requires that the cells be "from a single clone", which is confusing. It is not clear whether the word "from" implies specific method steps, or whether the cells are merely required to possess identical genetic characteristics. Clarification is required.

Claim Rejections - 35 USC § 102

Claims 1-4 and 18 are/remain rejected under 35 U.S.C. 102(b) as being anticipated by human bone marrow taken in light of Rafii et al. The claims are drawn to a composition comprising cells that give rise to both hematopoietic and endothelial lineages, said composition having numerous properties as recited in claim 1. In some dependent claims, the cells do not react with various markers.

Art Unit: 1651

In some dependent claims, the cells are human. In some dependent claims, the cells are from a single clone.

Bone marrow naturally comprises both endothelial precursor cells (EPCs) and hematopoietic stem cells (HSCs), as is reviewed by Rafii et al. (see, for example, Table 1). The preparation therefore differentiates to both hematopoietic and endothelial cell lineages. Bone marrow, and indeed the entire human body, arises from a single cell (the fertilized egg) and, as such, can be considered to be "from a single clone" as required by new claim 18. Because claim 18 would have been rejected under the same grounds as claims 1-4 had it been included in the original claim listing, no new grounds of rejection for this claim are required.

Applicant alleges that Rafii et al. is not prior art under section 102(b) because it was published after the filing of the priority documents. This argument has been fully considered, but it is not persuasive.

The examiner points out that this rejection was made over human bone marrow **in light of** Rafii et al., not over Rafii et al. *per se*. The Rafii et al. reference was merely cited as evidence of inherent characteristics of a prior art product, in this case human bone marrow. In certain circumstances, references cited to show a universal fact need not be available as prior art before applicant's filing date. *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962). Such facts include the characteristics and properties of a material or a scientific truism. Some specific examples in which later publications showing factual evidence can be cited include situations where the facts shown in the reference are evidence "that, as of an application's filing date, undue experimentation would have been

Art Unit: 1651

required, *In re Corneil*, 347 F.2d 563, 568, 145 USPQ 702, 705 (CCPA 1965), or that a parameter absent from the claims was or was not critical, *In re Rainer*, 305 F.2d 505, 507 n.3, 134 USPQ 343, 345 n.3 (CCPA 1962), or that a statement in the specification was inaccurate, *In re Marzocchi*, 439 F.2d 220, 223 n.4, 169 USPQ 367, 370 n.4 (CCPA 1971), or that the invention was inoperative or lacked utility, *In re Langer*, 503 F.2d 1380, 1391, 183 USPQ 288, 297 (CCPA 1974), or that a claim was indefinite, *In re Glass*, 492 F.2d 1228, 1232 n.6, 181 USPQ 31, 34 n.6 (CCPA 1974), **or that characteristics of prior art products were known**, *In re Wilson*, 311 F.2d 266, 135 USPQ 442 (CCPA 1962)." *In re Koller*, 613 F.2d 819, 823 n.5, 204 USPQ 702, 706 n.5 (CCPA 1980) (quoting *In re Hogan*, 559 F.2d 595, 605 n.17, 194 USPQ 527, 537 n.17 (CCPA 1977) (emphasis in original)). See M.P.E.P. §2124.

The rejection of claims 1-4 under section 102(b) as being anticipated by Reubinoff et al. is withdrawn in light of applicant's remarks and evidence in the specification pointed out by applicant regarding ES cells.

The rejection of claims 1-4 under section 102(b) as being anticipated by Choi et al. is withdrawn in light of applicant's remarks and the marker expression data in Choi et al. pointed out by applicant (Remarks, page 13, paragraph 3) as it relates to the markers in claim 2. The examiner notes for the record, however, that applicant's arguments (i)-(iii) are unpersuasive as to this rejection (Remarks, page 13, paragraphs 5-7). The mere fact that Choi et al. did not test their cells for the claimed characteristics does not necessarily indicate that the cells lack said characteristics.

Art Unit: 1651

No claims are allowed. No claims are free of the art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.**

See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Friday, 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

leb

Lora E Barnhart



SANDRA E. SAUCIER
PRIMARY EXAMINER